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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/077,521 | 02/15/2002 | James Edward Brebove | 0045-1 | 3492 |
| 7590 | 03/17/2004 | | EXAMINER | |
| Ernest D. Buff Ernest D. Buff & Associates, LLC 245 South Street Morristown, NJ 07960 | | | GOLLAMUDI, SHARMILA S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------|-----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/077,521 | BREHOVE, JAMES EDWARD |
| | Examiner | Art Unit |
| | Sharmila S. Gollamudi | 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 December 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Receipt of Amendments filed on December 24, 2003 is acknowledged. Claims 1-16 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Rejection of claims 1-5, and 11-16 under 35 U.S.C. 103(a) as being unpatentable over Sorenson et al (5,972,317) in view of Hsu et al (5,874,476) in further view of Saischek et al (4,608,440) is maintained.

Sorenson et al teach a method and composition for treating diseased nails. Sorenson teaches that the infiltration of fungal diseases result in nail disease. See column 1, lines 19-46. The nail composition includes a medicament and proteolytic enzymes to enhance penetration of the medicament in a 25:75 to 75:25 ratios. See abstract, column 3, lines 40-45, and column 4, lines 48-65. The medicament may be an

antibacterial, antifungal, or antimycotic agent. See example 1. Additionally, example 1 contains boric acid in the amount of 51.4 to 61.3%. Note boric acid is a conventional antifungal agent.

Sorenson et al do not specify the instant antifungal boric acid derivatives.

Hsu et al teach inhibiting the growth of microorganisms with dihalorformaldoxime carbamates and other conventional antimicrobials agents such as instant 1, 3, 2-dioxaborinane. See column 3, lines 6-63. The agents may be used in a variety of field such as cosmetics and toiletries.

Saischek et al teach 1, 3, 2-dioxaborinanes have outstanding fungicidal activity and algicidal activity. See column 1, lines 15-20. Saischek teaches the use of the boric acid containing compounds for a broad spectrum of harmful organisms from various fungal classes. See column 2, line 67 to column 3, lines 3. The reference teaches the use of hydrocarbons and mineral oil fractions as solvents for the agent. See column 4, lines 34-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sorenson et al and Hsu et al and utilize the instant antifungal. One would be motivated to do so since Hsu et al teach the conventional use of 1, 3, 2-dioxaborinane as antibacterial agents. Further, one would be motivated to utilize the instant agent among the conventional antibacterial agents provided by Hsu since Saischek et al disclose that 1, 3, 2-dioxaborinane have outstanding antifungal activities against various fungal classes. Therefore, one would be

motivated to use the instant antifungal to treat fungal nail diseases since they have excellent biocidal properties and Sorenson teaches the use of boric acid.

Response to Arguments

Applicant argues that the instant invention effectively kills the most common pathogens without skin irritation, which has been determined by in vivo tests. Applicant argues that Sorenson et al do not disclose the instant 1,3,2-dioxaborinane and that Sorenson et al's boric acid is not taught as the antifungal agent. It is argued that Sorenson et al teach proteolytic enzymes. Applicant argues that Hsu et al do not teach or suggest the use of the instant microbial agent for nail infections. It is argued that the instant antifungal is listed with a multitude of other microbial compounds in Hsu and thus, there is not motivation to utilize the instant compound. Applicant argues that Saischek et al does not teach the instant 1,3,2-dioxaborinane derivatives for the use of nail infections and does not disclose it would be suitable for animals. Applicant argues that the examples teach the use of the instant antifungal on plants and not animals.

Applicant's arguments have been fully considered but they are not persuasive. Firstly the examiner points out that the claims are rejected under obviousness and thus the primary reference need not anticipate the invention and disclose all instant limitation, it merely has to suggest the instant invention. The examiner points out that Sorenson teaches the method of treating nail infections utilizing a generic antifungal agent. Sorenson teaches that the medicament "may be any type of drug or medicament... Such medicaments may include anti-bacterial compositions, anti-mycotic or antifungal compositions..." Therefore, Sorenson clearly provides a suggestion to

modify the composition and include a medicament of choice, the only criteria being that it has microbial properties.

Although, Sorenson's boric acid is not taught as the antifungal agent, the examiner points out that the prior art does not have to state the function of every component in the composition since the function is implicit if the art teaches the component in a composition. Further, it is known in the art to utilize boric acid for antimicrobial purposes. The use of boric acid in Sorenson et al provides a skilled artisan motivation to utilize a boric acid derivative as the medicament without the risk of adverse effects.

The secondary reference is solely relied upon to teach the instant antifungal, which is a boric acid derivative. Hsu teaches the instant antifungal may be used in personal care products. The examiner acknowledges that the instant compound is taught among other compounds and thus relies on the teachings of Saischek et al to provide the motivation to utilize the 1,3,2-dioxaborinane derivatives out of the compounds taught by Hsu et al.

In regards to Saischek et al, firstly the examiner points out that the applicant has removed the limitation of "topical composition" and the claims now merely recite formulation claim with intended use. The phrase "for the topical treatment of nail infections" is intended use and does not hold patentable weight in product claims. Secondly, it is pointed out Saischek is solely relied upon to teach the superior antifungal properties of the instant 1,3,2-dioxaborinane derivative and to provide the motivation for one to utilize the instant antifungal over other antifungals known in the art. The primary

reference teaches the broad aspect of the instant composition and the method respectively. Hsu clearly teaches the instant antifungal for cosmetic compositions. Additionally, column 4, line 20 teaches the use of the instant antifungal in swimming pools and thus it is clear that the antifungal would contact the skin of those using the pool. Furthermore, the reference teaches the use of the antifungal in many a wide array of fields. In regards to the reference having only examples concerning plants, the examiner points out that disclosed examples and preferred embodiments do not constitute a teaching away from the broad disclosure or nonpreferred embodiments.

In regards to the proteolytic enzymes taught in Sorenson et al, the examiner points out that the instant claim language does not exclude other components such as Sorenson's enzymes in the composition.

Applicant argues that the Material Safety Data lists the hazards of the instant antifungal. It is argued that the reference states that it causes mild irritation to the skin at a working concentration, thus this teaches away from the application of the instant compound on the skin. Applicant claims the efficacy of the instant compound in *in vivo* tests.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that the claims do not recite any weight percentages of the compound nor recite any excipients in the independent claims that eliminate the "skin irritation". Further, the examiner has already supplied a reference wherein the instant compound is clearly utilized in personal care compositions; therefore this argument is moot. In regards to the data, the examiner points out that the applicant has not provided

the “*in vivo*” data to overcome the instant obviousness rejections and mere arguments are not enough to purport unexpectedness or “efficacy of a formulation”.

It should be noted that the examiner suggested a significant nail formulation, i.e. reciting a specific composition to overcome the art; however applicant merely amended the preamble. Therefore, the prior art still reads on the instant invention.

Rejection of claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Wohlrab et al (5,346,692) in view of Hsu et al (5,874,476) in further view of Saischek et al (4,608,440) is maintained.

Wohlrab et al teach a nail lacquer for the treatment of onychomycosis. The composition includes a cellulose derivative (film former), 1-50% of an antimycotically active substance, volatile solvents, urea (penetration enhancer), and plasticizers.

Sorenson et al do not specify the instant antifungal boric acid derivatives.

Hsu et al teach inhibiting the growth of microorganisms with dihalorformaldoxime carbamates and other conventional antimicrobials agents such as instant 1, 3, 2-dioxaborinane. See column 3, lines 6-63. The agents may be used in a variety of field such as cosmetics and toiletries.

Saischek et al teach 1, 3, 2-dioxaborinanes have outstanding fungicidal activity and algicidal activity. See column 1, lines 15-20. Saischek teaches the use of the boric acid containing compounds for a broad spectrum of harmful organisms from various fungal classes. See column 2, line 67 to column 3, lines 3. The reference teaches the use of hydrocarbons and mineral oil fractions as solvents for the agent. See column 4, lines 34-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wohlrab et al and Hsu et al and utilize the instant antifungal. One would be motivated to do so since Hsu et al teach the conventional use of 1, 3, 2-dioxaborinane as antibacterial agents. Further, one would be motivated to utilize the instant agent among the conventional antibacterial agents provided by Hsu since Saischek et al disclose that 1, 3, 2-dioxaborinane have outstanding antifungal activities against various fungal classes. Therefore, one would be motivated to use the instant antifungal to treat fungal nail diseases since they have excellent biocidal properties.

Response to Arguments

Applicant argues that Wohlrab et al do not teach instant active. It is argued that Wohlrab teaches antifungal agents that have been commonly used on humans. Applicant argues that the primary use of the instant active is for fuel additives and that the compounds are said to cause skin irritation at working concentrations. Applicant argues that is not obvious to combine Hsu et al and Saischek et al's teachings to obtain a topical nail formulation for treating nail infection.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that the claims are rejected under obviousness and thus the primary reference need not anticipate the invention and disclose all instant limitation, it merely has to suggest the instant invention. The examiner points out that Wohlrab teaches the method of treating nail infections utilizing an antifungal agent. The secondary reference is solely relied upon to teach the instant antifungal, which is a boric

acid derivative. Hsu teaches the instant antifungal may be used in personal care products, despite applicant's arguments that the instant compound is only utilized as a fuel additive. The examiner relies on Saischek et al to provide the motivation to utilize the instant 1,3,2-dioxaborinane derivatives.

In regards to the skin irritation caused by working concentrations, the examiner points out that the claims do not recite any weight percentages of the compound nor recite any excipients in the independent claims that eliminate the "skin irritation". Further the examiner has already supplied a reference wherein the instant compound is clearly utilized in personal care compositions; therefore this argument is moot.

It should be noted that the examiner suggested a significant nail formulation, i.e. reciting a specific composition to overcome the art; however applicant merely amended the preamble. Therefore, the prior art still reads on the instant invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG
[Signature]
March 9, 2004

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